

### REMARKS

Claims 54, 57-62, and 64-71 are pending in this application and are presented for reconsideration.

#### Rejection of Claims Under 35 USC § 103

Claims 57-66, 64, 65 and 67-71 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,630,924 to Fuchs et al. (Fuchs) alone. Applicants respectfully disagree.

Applicants respectfully submit that Fuchs does not teach peptide nucleic acid (PNA) probes detectably labeled for use in an incubation/separation device as presently claimed.

Contrary to the presently claimed invention, Fuchs teaches assay methods that require two binding partners:

- a) a first binding partner which comprises a detectable moiety but is not disclosed as comprising any PNAs ( see col. 8, lines 45-67 and col. 9, lines 1-8); and
- b) a second binding partner which comprises a charge modifying moiety but no labels, where the modifying moiety may comprise PNAs (see col. 8, line 45-67 col. 9, lines 9-32 and col. 10, lines 25-60).

Fuchs further explains the requirement for both binding partners in the following terms:

"By virtue of the ... detectable moiety attached to the first binding partner, the presence of such a complex is detectable ... An advantage of the instant invention relates directly to the discovery that bound second binding partner, as defined herein, permits separation of this three-membered complex from unbound first binding partner sufficient to permit reliable detection of the analyte-containing complex..." (col. 10, lines 11-19)

Fuchs recognizes the necessity of separating the bound first binding partners from the unbound binding partners to use detection of the label of the first binding partner as an indication of the presence of the analyte (see col. 10, lines 19-24). Separation of these two chemical entities is achieved by the use of a charge modifying moiety in the second binding partner. Thus, Fuchs teaches PNAs as a moiety for a non-labeled binding partner. However, it does not teach or

suggest that PNAs could or should be used as a labeled binding partner as is done in Applicants' invention.

In contrast, Applicants' claimed device requires a PNA probe labeled with a detectable moiety to be disposed within the device upstream of a separation zone. By using labeled PNA probes, Applicants can achieve good separation and identification of the chemical entities without the use of another binding reagent. Thus, Applicants submit that the presently claimed invention is patentable over Fuchs and respectfully request withdrawal of this rejection.

Also, Applicants submit that the inventors in the cited Fuchs reference and the present application were under an obligation to assign their respective inventions to the same entity, i.e. PerSeptive Biosystems, Inc., at the time the inventions described in the cited reference and the present application were made.

Claims 57-62, 64, 65, and 67-71 are further rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Fuchs taken in view of U.S. Patent No. 5,217,866 to Summerton et al. (Summerton).

Applicants respectfully request withdrawal of this rejection as the teachings of Summerton fails to cure the defects of Fuchs. Applicants have already reviewed the deficiencies of the teaching of Summerton to anticipate the methods (then claimed) and devices earlier in prosecution. Applicants reiterate these statements herein below as they remain applicable to the instantly claimed devices. These statements are applicable here to overcome the instant rejection as Summerton still fails to teach labeled PNA probes.

Unlike the instant methods, the methods disclosed in Summerton use labeling reagents separate from the PNA probes, such as dansylspermine, for detection of the bound analyte (Figure 14 and col. 23, lines 5-67). Further, these labeling reagents are designed to bind to the polynucleotide's phosphate groups by electrostatic interactions. Thus, these methods differ from the presently claimed methods in that the detectable moieties are not bound to the PNA probes. Also, in Summerton, the use of labeling reagents separate from the probes requires a supplemental separation step to remove the unbound labeling reagents from the labeled complex. In the instant methods, such step is avoided as the separation of the probe bound to the polynucleotide from the unbound probe occurs simultaneously from the separation of the labeled complex from the unlabeled complex. This is achieved by the use of labeled PNA probes.

(Excerpt from Applicants' reply mailed January 21, 1998). Applicants submit that the presently claimed devices are patentable over both Fuchs and Summerton and respectfully request withdrawal of this rejection.

Claims 54, 57, 58, 61, 62, and 65-68 are rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Patent No. 5,985,153 to Dolan (Dolan) in view of Summerton. Applicants respectfully traverse this rejection as the relevant disclosure of Dolan relied on by the Examiner is not available as prior art for the instant application.

The instant application was filed on October 4, 1996, claiming the benefit of a provisional application filed October 6, 1995.

Dolan is a patent that issued on an application filed on January 2, 1997. Dolan claimed the benefit of two earlier provisional applications filed respectively on June 7, 1996 (Serial No. 60/019,282) and November 5, 1996 (Serial No. 60/030,436).

It appears that Dolan is relied upon as an eligible prior art document under §102(e) as of the filing date of the earliest provisional application (Serial No. 60/019,282). However, to be effective as of the filing date of this provisional application, subject matter appearing in the printed patent and relied upon for making the rejection must be supported in the provisional application in the manner of §112, first paragraph. A review of the disclosure of Serial No. 60/019,282 showed that the text quoted in the Office Action and relied upon in rejecting the instant claims is absent from this provisional application (a copy of this provisional application is attached to this paper as Exhibit A). Therefore, Applicants submit that Dolan is not available as prior art and thus respectfully request that this rejection be withdrawn.



### CONCLUSION

Applicants respectfully submit that this Amendment and Response places the pending claims in condition for allowance. The Examiner is cordially invited to contact the undersigned by any means indicated below, if upon final review of this case, any impediment is found that prevents this case from proceeding to allowance.

Respectfully submitted,

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A handwritten signature in cursive script, appearing to read "Isabelle A. S. Blundell".

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